DEC - 2 2013

510(k) Summary

OPTIFIX™ Absorbable Fixation System — 10 July, 2013

Submitter: Davol Inc.
100 Crossings
Boulevard
Warwick, RI 02886

Contact: Radhika Pondicherry
Senior Regulatory Affairs Specialist
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Preparation Date: 10 July, 2013

Trade Name: OPTIFIX™ Absorbable Fixation System

Common/Classification Name: Staple Implantable/Implantable Staple

Regulatory Class: Class II per 21 CFR §878.4750

Product Code: GDW

Legally Marketed Predicate Device(s): K082396 Davol Absorbable Fastener System- SorbaFix™ - 02Jan2009

Device Description: The OPTIFIX™ Absorbable Fixation System is a sterile single use device that delivers either 15 or 30 synthetic absorbable fasteners via a straight shaft. The shaft of the OPTIFIX™ Absorbable Fixation System is 39 cm in length. The fasteners are designed with a retention feature on the end and are manufactured from Poly (D, L)-lactide.

Indications for Use: The OPTIFIX™ Absorbable Fixation System is indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.

Predicate Device Comparison

Device Comparison		
Device Features	OptiFix (Subject Device)	SorbaFix (K082396)
Tack Schematic		
Indication For use	Identical to predicate	Indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.
Fastener Material	Identical to predicate	Poly (D,L) Lactide

Fastener Violet Dye	Identical to predicate	D & C Violet No. 2
Fastener Body Contact	Identical to predicate	Long term implant (>30 days) contacting tissue and/or bone
Fastener Shape/Design	Push Tack with retention feature on end	Screw
Fastener Quantity per Device	15 & 30 fasteners	5,15& 30 fasteners
Deployment component - Shaft Length	39 cm in length	18cm and 36 cm in length
Deployment component Handle design	Identical to predicate	Pistol/Gun shape
Device Sterilization	Identical to predicate	Gamma Irradiation (25 - 40 kGy)

Non-Clinical Test Summary

The following non-clinical tests were completed for the subject and predicate devices. OptiFix™ passed all the test requirements and showed substantial equivalence to the results of the predicate device- SorbaFix™.

- Shear strength testing
- Mass loss determination
- Dimensional changes
- Inherent viscosity
- Glass transition temperatures
- Residual monomer content

All samples tested met the acceptance criteria.

Animal Test Summary

The following Animal in-vivo studies were completed

- Contracture
- Tissue Ingrowth
- Histology

Ex-vivo Burst Strength on Pig wall

OptiFix™ passed all the test requirements and showed substantial equivalence to the results of the predicate device- SorbaFix™.

Conclusions	The OPTIFIX™ Absorbable Fixation System is substantially equivalent to the predicate device. The device is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 2, 2013

C.R. Bard Incorporated
Radhika Pondicherry
Senior Regulatory Affairs Specialist
100 Crossing Boulevard
Warwick, Rhode Island 02886

Re: K132134
Trade/Device Name: OPTIFIX™ Absorbable Fixation System
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: October 29, 2013
Received: October 30, 2013

Dear Pondicherry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132134

Device Name
OPTIFIX™ Absorbable Fixation System

Indications for Use *(Describe)*

The OPTIFIX™ Absorbable Fixation System is indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

David Krause -S